

Outcome of the Process - Public Consultation on proposed Human Medicines, Medical Devices, Veterinary Medicines and Compliance Fees for 2020

1 NUMBER OF RESPONSES

The HPRA received two responses from industry representative groups, one response from a manufacturing company and one from a non-profit organisation.

The HPRA welcomes all the suggestions and contributions made and, while we are not always able to take on board the proposals, we would hope that this document provides an explanation for our approach.

2 SUMMARY OF RESPONSES RECEIVED

Human Medicine fees

Two responses were received from the human medicines industry representative groups. It was acknowledged that the HPRA has taken a supportive role this year in assisting companies in relation to Brexit, on the FMD directive and the work in the area of shortages was recognised. However, one of the group expressed disappointment with the proposed fee increases which would place an additional burden on their members. They noted that their members already face increased costs due to Brexit and the Falsified Medicines Directive. They also addressed other specific fee concerns such as pensions, inflation, litigations and the increase in the annual fee for manufacturing authorisations. Both groups recommended restraint in relation to increasing fees.

It was also suggested that there should be no increase to fees for clinical trials but the submission also recognised and welcomed that the HPRA continues to charge no fees for academic trials.

The response received from the manufacturing company raised a concern over the fee increases to the manufacturing authorisations annual maintenance fees and also raised other specific issues relating to the application of variation fees. We have responded directly to the company on the variation issue but are not proposing changes to these fees for 2020 but will keep the matter under review for 2021.

One organisation requested that we continue to waive the inspection fee for non-profit legal entities.

3 HPRA RESPONSE

The HPRA has reviewed and considered the above responses. The HPRA acknowledges that it is a difficult year for the pharmaceutical industry with Brexit and the additional responsibilities and costs arising out of the falsified medicines directive. In light of these considerations, we revisited the fee proposal and consequently we have reduced the general increase from 3% to 2%. In addition, we will apply no increase to the maintenance fee for products that are not marketed.

In relation to essential medicines with very small markets the HPRA will be very happy to engage with companies over the level of fees charged. In addition, the HPRA is committed to considering any issues including fees, arising from Brexit which may prevent market access, and we would encourage companies with any Brexit related issue to engage with the HPRA.

4 CONCLUSION

Overall, companies and their representative bodies expressed concerns about the fee increases. The HPRA has reflected the concerns in the proposal to limit the increase to 2% and freeze the fees for not marketed products. The HPRA's primary objective is the protection of public health but in delivering this we are committed to providing a first class service to the industry we regulate. We will continue to review the cost base of the HPRA and related fees. As always we commit to reviewing our fees annually to ensure that the fee levels are appropriate to the functions and costs of the HPRA.

Consequently, as we are required to cover our costs with fee income, we propose to submit the revised fee structure as outlined in the original consultation document to the Minister for Health and the Minister for Agriculture, Food and the Marine for approval.

We would like to thank all those that contributed to the consultation process.

HPRA
Finance, Corporate and International Department
28 November 2019